

Draft Guidance for Industry and FDA Staff-Hospital Bed System Guidance to  
Reduce Entrapment    Docket number 2004D-0343

Thank you for the opportunity to comment on the FDA draft guidance for Hospital Bed System Dimensional Guidance. We understand and appreciate the intention of This document, to minimize the potential of patient entrapment in a hospital bed.

Our pilot testing of existing beds within our facility indicates that 64% of our beds Fall outside of guidelines put forth in Zone 1 of Table 3 and 100% of our beds do not Fall within acceptable limits of Zone 5.

The areas of concern within Zone 1 can be corrected with an approved method Supplied by bed manufacturers and retrofitted onto existing beds.

The areas within Zone 5 are a little more complicated. To correct this condition All side rails would need to be replaced to fall within acceptable parameters. This Would still not address those conditions created when mattresses become compressed Or when the bed is articulated through its full range of motion.

Thank you again for the opportunity to comment.

David Ludlum  
Facilities Manager  
Mercy Medical Center  
Williston, ND

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